KEY INFORMATION FORM FOR T1D-TECH CHW

We are asking you to choose whether or not to volunteer for a research study about a diabetes research study called Type 1 Diabetes Technology & Community Health Workers (T1D-Tech CHW). We are working to test a new care program created for young adults with T1D that will encourage and support diabetes technology use. Community health workers (CHW) will provide young adults with hands-on technology education, assist with goal-setting, peer support, and social needs management. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The 6 month diabetes program consists of weekly individual sessions with a young adult community health workers in Month 1 (4 sessions), bi-weekly individual sessions in Months 2 and 3 (4 sessions), less intensive individual sessions in Months 4-6 (3 sessions), and an option for monthly CHW-led peer group sessions throughout. CHWs will provide participants with hands-on technology education, device onboarding support, and motivation and encouragement to set and attain goals. In addition they will also act as “healthcare provider support” by shifting education, insurance, device onboarding, and support tasks away from busy providers, and act as communication links between patients and providers.CHW individual and group sessions will be held via videoconferencing or in person, per participant preference and institution COVID-19 rules. Intervention participants will also be able to communicate with CHWs on-demand by text message, phone/video call, or in person.

By doing this study, we hope use knowledge gained to offer a new potentially sustainable T1D care approach aimed at root causes of disparities. In addition, we will gain knowledge on T1D technology care in primary care settings.

Your participation in this research will last about 6 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We are asking you to join this study because your doctor identified you as someone eligible to participate based on your age, type 1 diabetes diagnosis, and are not currently on diabetes technology. For a complete description of benefits, refer to the Consent Document below. The possible benefits of taking part in this study include access to a CHW staff member who could provide extra outreach, potential in increased use of diabetes technology, social needs assessment and referrals, and help with patient advocacy from someone with shared background and cultural values.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

We do not think there are any physical risks related to participating in this research study. There is a possibility that you may feel a sense of undue burden from study procedures or in the frequency of contact with the CHW. We have made participation voluntary However, a risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. *For a complete description of risks, refer to the Consent Document below.*
For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You do not have to participate. It is your choice. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Shivani Agarwal. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 646-592-4506. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einsteinmed.org.

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called ***Type 1 Diabetes Technology & Community Health Workers (T1D-Tech CHW)*** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Dr. Shivani Agarwal . You can reach Dr. Agarwal at:

Office Address: 1180 Morris Park Ave

Bronx, NY, 10461
Telephone #: 646-592-4506
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by the National Institutes of Health: *National Insitute of Diabetes and Digestive and Kidney Diseases*

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einsteinmed.org , or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Why is this study being done?

The goal of this study is to increase technology use by using a community health worker and their unique position to establish trust and increase under-represented minority young adult autonomy, competence, and social support, while enhancing team-based care by filling provider workforce gaps. We believe CHWs have a strong evidence base of effectiveness in reducing inequity among underserved diabetes populations but they have not been tested to reduce growing inequity in T1D technology use. We hypothesize that our use of CHWs in the T1D technology context will demonstrate promising efficacy and outcomes. Our study is being conducted to directly address root causes of disparities by focusing on targets like inequities in healthcare delivery and social needs.

Why am I being asked to participate?

You are being asked to participate in this study because your doctor identified you as someone eligible to participate based on your age, type 1 diabetes diagnosis, and are not currently on diabetes technology. You also meet the study inclusion criteria of (1) T1D duration ≥6 months;

(2) 18-30 years old; (3) Self-identified URM status: non-Hispanic Black or Hispanic; (4) English- or Spanish-speaking; and (5) Not currently on diabetes technology (includes never offered, discontinued, or previously refused technology). We plan to enroll 130 young adults with type 1 diabetes from the Supporting Emerging Adults with Diabetes (SEAD) program at the Fleischer Institute at Einstein (Bronx, NY) and Montefiore Medical Center primary care and endocrinology clinics.

<u>What will happen if I participate in the study?</u>

If you say yes, you will first be screened eligible for the study, then you will have a virtual baseline study visit for all explanations of procedures. Please refer to the Figure for the following explanation of the timeline of the study procedures. After you are randomized, those randomized into the T1D TechChW arm, CHWs will conduct weekly individual sessions with you in Month 1 (4 sessions total), then bi-weekly individual sessions in Months 2 and 3 (4 sessions), and finally less intensive individual sessions in Months 4-6 (3 sessions). You will also be giving an option for monthly CHW-led peer group sessions throughout (total 6-mo study period=11 individual and 6 potential group sessions)

CHW individual and group sessions will be held via videoconferencing or in person, based on your preference and institution COVID-19 rules. Intervention participants will also be able to communicate with CHWs on-demand by text message, phone/video call, or in person

You will also complete participant self report questionnaires and partake in interviews at baseline, 3 and 6 month mark.

Through these CHW sessions you will be able to participate in hands-on individual sessions that will introduce tech with device demos/videos, have in-depth discussions of fears, barriers, beliefs, and methods to overcome these beliefs, partake in goal-setting and receive social needs assessments. You will also receive education on insurance navigation and authorization paperwork, how to obtain a device via mail-in pharmacy. You will receive aid in setting up device training and attendance, if desired. And receive on-demand support for issues that arise in the critical 1-month post study period.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S.law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As part of this study we will review your medical records and put the information we collect in our research records.

<u>How many people will take part in the research study?</u>

You will be one of about 130 people who will be participating in this study. The study will be conducted at Montefiore Medical Center/Albert Einstein College of Medicine.

<u>Will there be audio and/or video recording?</u>

Participants' post-intervention interviews will be audio-record and transcribed, however; no identifying characteristics of individuals will be published or presented. These recordings will only be used for tabulation of specific criteria by the research team. The confidentiality of data will be maintained by using research identification numbers that uniquely identify each individual. Safeguards will be established to ensure the security and privacy of participants′ study recordings. All recordings will be destroyed after study analysis for intervention fidelity.

Study participants face risks related to inadvertent release of confidential information. This will be minimized through careful adherence to best practices for data collection and management such as audio/video recording. All research staff will be trained in principles and methods for assuring participant confidentiality and safety. Efforts, such as keeping research records secure and allowing only authorized people to have access to research records, will be made to keep the information safe. Data will be used only in aggregate and no identifying characteristics of individuals will be published or presented. Confidentiality of data will be maintained by using research identification numbers that uniquely identify each individual. Safeguards will be established to ensure the security and privacy of participants' study records. Databases will not use participants' names as identifiers: a research ID number will be used. The research records will be kept in a locked room in the study offices. The files matching participants' names and demographic information with research ID numbers will be kept in REDCap with restricted access. Only study personnel will have access to these files, and they will be asked to sign a document that they agree to maintain the confidentiality of the information. After the study is completed, data will be stored with other completed research studies in a secured storage vault.

Information Banking (Future Use and Storage)

No Data is Stored

Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will receive a total of $350 for this study over the 6 month period. If you choose to withdraw from the study before all visits are completed, you will be paid only for the sessions you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any times you would not keep my data confidential?
If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities. Additionally, if you give us information that you may hurt yourself or that you may hurt someone else, we authorized to report this.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

We do not think there are any physical risks related to participating in this research study.

The risks of participation are minimal. Below are some potential risks that may or may not be related to study participation.

Undue burden of study procedures. There is a possibility that you may feel a sense of undue burden from study procedures or in the frequency of contact with the CHW interventionist. We have made participation voluntary.
Expression of intent to harm self and/or others. Given the high frequency of psychological disorders in YA, you may express intent to harm yourself and/or others during participation in the trial. Study staff and CHWs will be trained on how to appropriately respond to expression of intent to harm self or others, and will maintain a Manual of Procedures (MOP). Healthcare providers will also be alerted about concerns regarding risk, with the participant's consent, unless per mandated reporting. Per New York State law, expression of intent to harm self or minors or the elderly are part of mandated reporting, and will be communicated in the consent procedures of the study, as previously done in our studies and with our staff.
Severe hypoglycemia requiring assistance. The initiation of diabetes technology may change diabetes management behaviors by increasing adherence to insulin dosing, which has a theoretical risk of mild (blood glucose 55-70 mg/dl) or severe hypoglycemia (blood glucose ≤54 mg/dl) requiring assistance (glucagon, EMS, ER visit, hospitalization).
Breach of Confidentiality. Taking part in this research study may involve providing information that you consider confidential or private. As in all research studies, there is a slight risk of a breach of confidentiality. You will be informed of confidentiality limitations in the informed consent. As described in detail below, every effort will be made to keep your name and contact information secure; only study staff will have access to linked contact information and study data. Identifiers will be excluded from any participant for data analysis.
Alternative Treatments and Procedures. The alternative to participation is for you to not participate in the study. If you decline to enroll in the study but express interest in accessing care, we will inform them of the procedures to do so.

Questionnaire

You may be uncomfortable answering some of the baseline questionnaires and post-intervention interview questions. It is possible that you may find these questionnaires to be mildly upsetting. Similar questionnaires have been used in previous research and these types of reactions have been uncommon. You may choose to not answer questions. You do not have to answer all the questions and you may stop at any time. We will do our best to keep your information safe by using a special code in research records.

New Findings

If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Are there possible benefits to me?

The potential benefits of the proposed research include access to a CHW staff member who could provide extra outreach, potential in increased use of diabetes technology, social needs assessment and referrals, and help with your patient advocacy from someone with shared background and cultural values. Benefits also include the overall contribution to knowledge for an understudied YA population and the potential to improve distal outcomes like HbA1c, diabetes distress, quality of life, and patient-provider satisfaction.

Alternative Proposals

The alternative is for potential subject to not participate in the study. If potential participants decline to enroll in the study but express interest in accessing care, we will inform them of the procedures to do so.

Are there any consequences to me if I decide to stop participating in this study?

If you decide to take part in the study, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at your facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she/he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if during the study the expression of intent to harm self or others is mentioned. If developed over the course of the study and identified, that participant will be withdrawn from the study but their data accruing until the point of withdrawal may be used.

In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

Do you have any questions?

Do you voluntarily consent to participate in this research? (Record potential subject's response)
[ ] Yes [ ] No

______________________	__________
Printed name of participant	Date

______________________	____________________________________	__________
Printed name of the person conducting the consent process	Signature	Date